

# Exhibit 2

**§ 1.132. Definitions.**

The following words and terms, when used in this ~~undesignated head~~subchapter, shall have the following meanings unless the context clearly indicates otherwise.

(1) Anatomical remains--The remains of a human body donated for the purposes of teaching or research to a medical school, a teaching hospital, or a medical research facility, after the completion of the activities for which the body was donated.

(2) Animal waste--Animal waste includes:

(A) carcasses of animals intentionally exposed to pathogens;

(B) body parts of animals intentionally exposed to pathogens;

(C) whole bulk blood and blood products, serum, plasma, and other blood components from animals intentionally exposed to pathogens; and

(D) bedding of animals intentionally exposed to pathogens.

(3) Approved alternate treatment process--A process for waste treatment which has been approved by the ~~Texas Department of Health~~department in accordance with § 1.135 of this title (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities).

(4) Biological indicators--Commercially-available microorganisms (e.g., United States Food and Drug Administration-approved strips or vials of Bacillus species endospores) which can be used to verify the performance of waste treatment equipment and/or processes.

(5) Blood and blood products--All waste bulk human blood, serum, plasma, and other blood components.

(6) Body fluids--Those free-flowing body substances other than blood, plasma, or serum identified under universal precautions as recommended by the United States Centers for Disease Control and Prevention, and includes, but are not limited to:

(A) semen;

(B) vaginal secretions;

(C) any body fluid containing visible blood;

(D) saliva in dental settings;

(E) amniotic fluid;

(F) cerebrospinal fluid;

(G) peritoneal fluid;

- (H) pleural fluid;
  - (I) pericardial fluid; and
  - (J) synovial fluid.
- (7) Bulk--A containerized, aggregate volume of 100 milliliters (mL) or more.
- (8) Bulk human blood, bulk human blood products, and bulk human body fluids--All free flowing waste: human blood; serum; plasma; other blood components; and body fluids; including disposable items saturated with blood or body fluids.
- (9) Burial--The act of depositing a pathological waste in a grave, a crypt, vault, or tomb, or at sea.
- (10) Burial park--A tract of land that is used or intended to be used for the interment of pathological waste in graves.
- (11) Cemetery--A tract of land that is used or intended to be used for the permanent interment of pathological waste, and includes:
- (A) a burial park for earth interments;
  - (B) a mausoleum for crypt or vault interments;
  - (C) a columbarium for cinerary interments; or
  - (D) a combination of one or more thereof.
- (12) Challenge waste load--A surrogate waste load assembled for use during waste treatment protocols to evaluate the efficacy of microbial inactivation processes. The composition of the challenge waste load will vary depending on the technology being evaluated.
- (13) Chemical disinfection--The use of a chemical agent to reduce significantly the numbers of active microorganisms, but not necessarily their endospores, from the surfaces of inanimate objects.
- (14) Chlorine disinfection/maceration--The process of shredding waste in the presence of a chlorine solution under negative pressure.
- (15) Columbarium--A structure or room or other space in a building or structure of most durable and lasting fireproof construction; or a plot of earth, containing niches, used, or intended to be used, to contain cremated pathological waste.
- (16) Contagious--Capable of transmission from human or animal to human.
- (17) Contaminated--The presence or the reasonably anticipated presence of blood or those body fluids as defined elsewhere in this section.

~~(18) Cremated remains--The bone fragments remaining after the cremation process, which may include the residue of any foreign materials that were cremated with the pathological waste.~~

(18) Cremation--The irreversible process of reducing tissue or remains to ashes or bone fragments through extreme heat and evaporation. Under this subchapter, this term includes the process of incineration.

(19) Crematory--A building or structure containing one or more furnaces used, or intended to be used, for the reduction (by burning) of pathological waste to cremated remains.

(20) Crypt or vault--The chamber in a mausoleum of sufficient size to inter the uncremated pathological waste.

(21) Department--The Texas Department of [State Health Services](#).

(22) Deposition in a sanitary landfill--Deposition in a sanitary landfill in accordance with 30 TAC Chapter 330.

(23) Discharge to sanitary sewer system--A discharge or flushing of waste into a sanitary sewer system which is done in accordance with provisions of local sewage discharge ordinances.

(24) Disinfection--A somewhat less lethal process compared to sterilization which destroys or inactivates viruses, fungi, and bacteria (but not necessarily their endospores) on inanimate surfaces.

(25) Encapsulation--The treatment of waste using materials which, when fully reacted, will encase such waste in a solid protective matrix.

(26) Entombment--The permanent interment of pathological waste in a crypt or vault.

(27) Executive Commissioner--In this title, Executive Commissioner means the Executive Commissioner of the Health and Human Services Commission.

(28) Fetal Tissue--A fetus, body parts, organs or other tissue from a pregnancy. This term does not include the umbilical cord, placenta, gestational sac, blood or body fluids.

(29) Grave--A space of ground in a burial park that is used, or intended to be used for the permanent interment in the ground of pathological waste.

~~(2830)~~ Grinding--That physical process which pulverizes materials, thereby rendering them as unrecognizable, and for sharps, reduces the potential for the material to cause injuries such as puncture wounds.

~~(2931)~~ Immersed--A process in which waste is submerged fully into a liquid chemical agent in a container, or that a sufficient volume of liquid chemical agent is poured over a containerized waste, such that the liquid completely surrounds and covers the waste item(s) in the container.

(~~30~~32) Incineration--That process of burning SWFHCRF in an incinerator as defined in 30 TAC Chapter 101 under conditions in conformance with standards prescribed in 30 TAC Chapter 111 by the Texas ~~Natural Resource Conservation~~ Commission on Environmental Quality.

(~~31~~33) Interment--The disposition of pathological waste ~~by using the process of~~ cremation, entombment, burial, or placement in a niche or by using the process of cremation followed by placement of the ashes in a niche, grave, or scattering of ashes as authorized by law, unless prohibited by this subchapter.

(~~32~~34) Log~~[sub]10[/sub]~~--Logarithm to the base ten.

(~~33~~35) Log~~[sub]10[/sub]~~ reduction--A mathematically defined unit used in reference to level or degree of microbial inactivation. A 4 log~~[sub]10[/sub]~~ reduction represents a 99.99% reduction in the numbers of active microorganisms, while a 6 log~~[sub]10[/sub]~~ reduction represents a 99.9999% reduction in the numbers of active microorganisms .

(~~34~~36) Mausoleum--A structure or building of most durable and lasting fireproof construction used, or intended to be used, for the entombment pathological waste.

(~~35~~37) Microbial inactivation--Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 log~~[sub]10[/sub]~~ reduction or greater; and inactivation of Bacillus subtilis endospores or Bacillus stearothermophilus endospores at a 4 log~~[sub]10[/sub]~~ reduction or greater.

(~~36~~38) Microbiological waste--Microbiological waste includes:

- (A) discarded cultures and stocks of infectious agents and associated biologicals;
- (B) discarded cultures of specimens from medical, pathological, pharmaceutical, research, clinical, commercial, and industrial laboratories;
- (C) discarded live and attenuated vaccines, but excluding the empty containers thereof;
- (D) discarded, used disposable culture dishes; and
- (E) discarded, used disposable devices used to transfer, inoculate or mix cultures.

(~~37~~39) Moist heat disinfection--The subsection of:

- (A) internally shredded waste to moist heat, assisted by microwave radiation under those conditions which effect disinfection; or
- (B) unshredded waste in sealed containers to moist heat, assisted by low-frequency radiowaves under those conditions which effect disinfection, followed by shredding of the waste to the extent that the identity of the waste is unrecognizable.

(3840) Niche--A recess or space in a columbarium used, or intended to be used, for the permanent interment of the cremated remains of pathological waste.

(3941) Parametric controls--Measurable standards of equipment operation appropriate to the treatment equipment including, but not limited to pressure, cycle time, temperature, irradiation dosage, pH, chemical concentrations, or feed rates.

(4042) Pathological waste--Pathological waste includes but is not limited to:

(A) human materials removed during surgery, labor and delivery, autopsy, embalming, or biopsy, including:

- (i) body parts;
- (ii) tissues or fetuses;
- (iii) organs; and
- (iv) bulk blood and body fluids;

(B) products of spontaneous or induced human abortions, regardless of the period of gestation, ~~including~~ except as provided by §1.133 of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services) including:

- (i) body parts;
- (ii) tissues or fetuses;
- (iii) organs; and
- (iv) bulk blood and body fluids;

(C) laboratory specimens of blood and tissue after completion of laboratory examination; and

(D) anatomical remains.

(4143) Saturated--Thoroughly wet such that liquid or fluid flows freely from an item or surface without compression.

(4244) Sharps--Sharps include, but are not limited to the following materials:

(A) when contaminated:

- (i) hypodermic needles;
- (ii) hypodermic syringes with attached needles;
- (iii) scalpel blades;

(iv) razor blades, disposable razors, and disposable scissors used in surgery, labor and delivery, or other medical procedures;

(v) intravenous stylets and rigid introducers (e.g., J wires);

(vi) glass pasteur pipettes, glass pipettes, specimen tubes, blood culture bottles, and microscope slides;

(vii) broken glass from laboratories; and

(viii) tattoo needles, acupuncture needles, and electrolysis needles;

(B) regardless of contamination:

(i) hypodermic needles; and

(ii) hypodermic syringes with attached needles.

(~~43~~45) Shredding--That physical process which cuts, slices, or tears materials into small pieces.

(~~44~~46) Special waste from health care-related facilities--A solid waste which if improperly treated or handled may serve to transmit an infectious disease(s) and which is comprised of the following:

(A) animal waste;

(B) bulk blood, bulk human blood products, and bulk human body fluids;

(C) microbiological waste;

(D) pathological waste; and

(E) sharps.

(~~45~~47) Steam disinfection--The act of subjecting waste to steam under pressure under those conditions which effect disinfection. This was previously called steam sterilization.

(~~46~~48) Thermal inactivation--The act of subjecting waste to dry heat under those conditions which effect disinfection.

(~~47~~49) Unrecognizable--The original appearance of the waste item has been altered such that neither the waste nor its source can be identified.

**§ 1.133. Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services.**

(a) Exemptions.

(1) Unless an item is specifically exempted, all special waste from health care-related facilities must be treated as provided in these sections.

(2) These sections do not apply to:

(A) teeth;

(B) human tissue, including fetal tissue, donated for research or teaching purposes, with the consent of the person authorized to consent as otherwise provided by law, to an institution of higher learning, medical school, a teaching hospital affiliated with a medical school, or to a research institution or individual investigator subject to the jurisdiction of an institutional review board required by 42 United States ~~Codes~~Code 289;

(C) placentas designated for sale and obtained from a licensed hospital or a licensed birthing center;

(D) in vitro tissue cultures that have not been intentionally exposed to pathogens;

(E) any material included in the definition of special waste from health care-related facilities which has been sold, donated, or in any way transferred from one health care-related facility to a subsequent facility(s) and other entities specified in subparagraph (B) of this paragraph for research or teaching purposes until it is discarded; ~~and~~

(F) disposition of fetal remains of a single pregnancy, body parts, or tissue (including bulk blood), transferred for disposition to a licensed funeral director in accordance with the Health and Safety Code, Chapter 711, and Chapter 181 of this title (relating to Vital Statistics) with the consent of the person or persons authorized to consent to the disposition of the fetal remains, body parts, or tissue (including bulk blood). All subcategories of pathological waste, unless otherwise exempted, must be treated and disposed of in accordance with §1.136 of this title (relating to Approved Methods of Treatment and Disposition).

(G) human tissue, including fetal tissue, that is expelled or removed from the human body once the person is outside of a healthcare facility;

(H) fetal remains required to be released to the parent of an unborn child pursuant to Texas Health and Safety Code, §241.010; and

(I) a placenta removed from a hospital or birthing center pursuant to Texas Health and Safety Code, Chapter 172.

(b) Minimum parametric standards for waste treatment technologies previously approved by the ~~Texas Department of Health.~~department.



(1) Chemical disinfection.

(A) Waste treatment via direct contact with chemical agents only shall utilize a registered chemical agent or an approved unregistered chemical agent as follows.

(i) Registered chemical agents.

(I) The chemical agent used shall be registered with the United States Environmental Protection Agency and the Texas Department of Agriculture.

(II) The chemical agent shall be used according to the manufacturer's instructions.

(ii) Unregistered chemical agents.

(I) Those unregistered chemical agents previously approved are:

(-a-) a freshly prepared solution of household chlorine bleach diluted 1:10 (volume/volume) with water; or

(-b-) a solution of 70% by volume 2-propanol (isopropyl alcohol).

(II) The containerized waste items shall be totally immersed in either solution for a period of time not less than three minutes.

(B) If a chemical agent has been included by a manufacturer of a commercially-available waste treatment technology as the principle step in the treatment process, then:

(i) the chemical agent (or its precursor(s)) or the microbial inactivating process must be registered with the United States Environmental Protection Agency for the purpose of waste treatment; or

(ii) the manufacturer must provide evidence that the technology utilizing said chemical agent (or its precursor(s)) or the microbial inactivating process has been approved for use in another state; or

(iii) the manufacturer must obtain approval for the process in accordance with §1.135 of this title (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities).

(C) Waste immersed in a liquid chemical agent must be thoroughly drained before disposal.

(2) Chlorine disinfection/maceration.

(A) The waste must be shredded prior to or during treatment and made unrecognizable as to source.

(B) The chlorine solution must have a free available chlorine concentration of at least 1,100 parts per million (ppm) when applied to the waste.

(C) The chlorine solution must be drained from the waste prior to disposal.

(3) Moist heat disinfection. Moist heat disinfection shall utilize either of the following processes.

(A) When subjecting internally shredded waste to moist heat assisted by microwave radiation, the temperature of the waste must reach at least 95 degrees Celsius under atmospheric pressure for at least 30 minutes.

(B) When subjecting unshredded waste in sealed containers to moist heat assisted by low-frequency radiowaves, the temperature of the waste must reach at least 90 degrees Celsius under atmospheric pressure for at least two hours, followed by shredding of the waste to the extent that the identity of the waste is unrecognizable.

(4) Steam disinfection. Steam disinfection shall meet all of the following requirements.

(A) To allow for sufficient steam access to or penetration of the waste, the waste shall be:

(i) packaged according to the recommendations provided by the manufacturer; and

(ii) loaded into the chamber so as to not exceed the capacity limits as set by the manufacturer.

(B) When subjecting waste to steam under pressure, the temperature in the chamber of the autoclave must reach at least 121 degrees Celsius and there must be at least 15 pounds per square inch gauge pressure for at least 30 minutes.

(C) The autoclave must be operated according to the manufacturer's instructions.

(5) Thermal inactivation. Thermal inactivation shall meet all of the following requirements.

(A) To allow for sufficient dry heat access to or penetration of the waste, the waste shall be:

(i) packaged according to the recommendations provided by the manufacturer; and

(ii) loaded into the chamber so as to not exceed the capacity limits as set by the manufacturer.

(B) Waste shall be subjected to dry heat of at least 160 degrees Celsius under atmospheric pressure for at least two hours.

(C) Waste shall be subjected to dry heat according to the manufacturer's instructions.

**§ 1.134. Application.**

(a) This subchapter may not be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted to be disclosed by state or federal privacy or confidentiality laws. This subchapter does not require the issuance of a birth or death certificate for the proper disposition of special waste from health care-related facilities. This subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue.

(b) These sections apply to special waste from health care-related facilities generated by the operation of the following publicly or privately owned or operated health care-related facilities, including but not limited to:

- (1) ambulatory surgical centers;
- (2) abortion clinics;
- (3) birthing centers;
- (4) blood banks and blood drawing centers;
- (5) clinics, including but not limited to medical, dental, veterinary;
- (6) clinical, diagnostic, pathological or biomedical research laboratories;
- (7) educational institution health centers;
- (8) educational institution research laboratories;
- (9) electrolysis facilities;
- (10) emergency medical services;
- (11) end stage renal dialysis facilities;
- (12) freestanding emergency medical care facilities;

(13) funeral establishments;

- ~~(13)~~(14) home and community support services agencies;
- ~~(14)~~(15) hospitals;
- ~~(15)~~(16) long term care facilities;

~~-(16)~~(17) facilities providing mental health and intellectual disability services, including but not limited to hospitals, schools, and community centers;

- (~~17~~18) minor emergency centers;
- (~~18~~19) occupational health clinics and clinical laboratories;
- (~~19~~20) pharmacies;
- (~~20~~21) pharmaceutical manufacturing plants and research laboratories;
- (~~21~~22) professional offices, including but not limited to the offices of physicians, ~~and~~ dentists, and acupuncturists;
- (~~22~~23) special residential care facilities;
- (~~23~~24) tattoo studios; and
- (~~24~~25) veterinary clinical and research laboratories.

**§ 1.135. Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities .**

All manufacturers of commercially-available alternate technologies, equipment, or processes designed or intended for the treatment of special waste from health care-related facilities, except those meeting the standards of § ~~1.133~~ 1.133(b) of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services), shall apply to the ~~Texas Department of Health~~-(department) on forms prescribed by the department for approval of said technologies, equipment, or processes to ensure that established performance standards are met.

(1) Levels of microbial inactivation.

(A) All laboratory evidence submitted to the department for review shall be provided by a laboratory that meets the standards of either the NSF International, the American Association for Laboratory Accreditation, or other accrediting agencies or organizations as approved by the department.

(B) All manufacturers of commercially-available alternate technologies, equipment, or processes designed and intended for the treatment of special waste from health care-related facilities shall provide specific laboratory evidence that demonstrates:

(i) inactivation of representative samples of vegetative bacteria, mycobacteria, lipophilic/hydrophilic viruses, fungi, and parasites at a level of 6 log~~[sub]~~10~~/sub]~~ reduction or greater, as determined by the department; and

(ii) inactivation of *Bacillus stearothermophilus* endospores or *Bacillus subtilis* endospores at a level of 4 log~~[sub]~~10~~/sub]~~ reduction or greater, as determined by the department.

(C) One or more representative surrogate microorganisms from each microbial group shall be used in treatment efficacy evaluation. The department shall determine the appropriate microorganisms to serve as representative surrogate microorganisms.

(D) The department shall prescribe those categories (types) and percent composition of special waste from health care-related facilities that present the most challenge to said treatment effectiveness under normal operating conditions of the equipment or process.

(E) Protocols developed for efficacy testing shall incorporate, as applicable, recognized, standard procedures. The protocols shall be congruent with the treatment method under review . The department shall determine the specific pieces of information to be provided by the manufacturer to assure a thorough evaluation of the alternate treatment technology.

(2) Documentation requirements.

(A) The manufacturer of the alternate treatment technology, equipment, or process shall provide to the department the following information:

(i) a detailed description of the treatment equipment, equipment specifications, operating instructions, and parameters of normal operation, and information detailing the intended use and typical site for which the equipment is designed;

(ii) complete documentation that the alternate treatment technology, equipment, or process meets microbial inactivation criteria for all required representative microorganisms for all department-specified challenge waste load compositions, including a description of the test methods used, and, upon request, the original data from test procedures conducted by the manufacturer;

(iii) documentation on available parametric controls, and, where technically feasible, evidence that demonstrates the efficacy relationship between biological indicator data and data derived from real-time parametric monitoring equipment;

(iv) details relating to waste residues including their potential hazards/toxicities and their specific mode of disposal or recycling;

(v) documentation providing occupational health assurance, and the means of providing required training in equipment operations;

(vi) evidence of United States Environmental Protection Agency registration and Texas Department of Agriculture registration for those treatment processes that employ a chemical agent to inactivate microorganisms, or evidence of approval of the treatment process by a state other than Texas;

(vii) documentation that user verification testing protocols are workable and valid; and

(viii) documentation of approval of the alternate treatment process or technology in other state(s) utilizing performance standard review, if applicable.

(B) Documentation must be submitted to the ~~Texas Department of Health, Bureau of Environmental Health on these~~[department on](#) forms provided by the department.

(3) Alternate treatment technology approval conditions.

(A) The alternate treatment technology approval is contingent upon the following conditions:

(i) Alternate treatment technology approval is granted only for the conditions specified in the manufacturer's instructions, equipment specifications, and operating procedures and conditions, including but not limited to:

(I) treatment time(s);

(II) temperature(s);

(III) pressures;

(IV) chemical concentration(s);

- (V) irradiation dose(s);
- (VI) feed rate(s); and
- (VII) waste load composition(s).

(ii) Any significant revision on the part of the manufacturer to either the operating conditions of the equipment's existing process or technology, or the fundamental principles of the process itself, i.e., the equipment now utilizes a different technology in part or altogether, will require re application for approval to the department.

(B) Prior approval granted by a state other than Texas that utilizes a performance standards approach to review alternate treatment technologies shall be considered as a basis for approval by the department if the department is provided with a valid and current approval, license, or permit issued by such state and substantial evidence to indicate that the performance standards upon which the approval, license, or permit was issued are equal to or more stringent than the performance standards included in this section.

(C) Facilities are not obligated to petition the department for approval for previously approved waste treatment technology they have currently on site, but the following items will apply should current equipment be replaced, regardless of reason:

(i) if the new equipment reflects a previously approved technology and is operated in accordance with §1.133(b) of this title, then purchase and installation can proceed without further action on the part of the department or the purchaser; or

(ii) if the new equipment represents an alternate treatment technology subject to prior approval by the department, based on performance standards as outlined in this section, then it is the purchaser's responsibility to ensure that the manufacturer has obtained such approval prior to purchase.

(4) Fees and annual listing.

(A) Initial application fee.

(i) The department shall charge an initial application fee for the evaluation of an alternate treatment technology pursuant to this section in the amount of \$4,000.

(ii) The initial application fee must be paid in full before the department undertakes its evaluation of the manufacturer's alternate treatment technology .

(B) Annual listing.

(i) Alternate treatment technologies must be listed at the time of the manufacturer's first sale of the product in Texas and prior to the product's purchase by a health care-related facility or any other person.

(ii) Failure by the manufacturer to maintain the listing after purchase does not preclude use of the alternate treatment technology, its transfer or re-sale, so long as compliance with §1.136(c) of this title (relating to Approved Methods of Treatment and Disposition) is achieved.

(iii) The department shall maintain a list of those approved alternate treatment technologies, including manufacturer, product name, model number, or other appropriate identifying information. The list shall be made available and distributed upon request by contacting the department.



**§ 1.136. Approved Methods of Treatment and Disposition.**

(a) Introduction. The following treatment and disposition methods for special waste from health care-related facilities are approved by the ~~Texas Board of Health (board)~~department for the waste specified. Where a special waste from a health care-related facility is also subject to the sections in Chapter 289 of this title (relating to Radiation Control), the sections in Chapter 289 shall prevail over the sections in this ~~undesignated head~~subchapter. Disposal of special waste from health care-related facilities in sanitary landfills or otherwise is under the jurisdiction of the Texas ~~Natural Resource Conservation~~ Commission on Environmental Quality and is governed by its rules found in ~~Title 30, Texas Administrative Code, Chapter 330.~~ 30 TAC Chapter 326 (relating to Medical Waste Management) and Chapter 330 (relating to Municipal Solid Waste).

(1) Animal waste. Animal waste shall be subjected to one of the following methods of treatment and disposal.

(A) Carcasses of animals intentionally exposed to pathogens shall be subjected to one of the following methods of treatment and disposal:

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) incineration followed by deposition of the residue in a sanitary landfill;
- (iii) carcasses of animals intentionally exposed to pathogens which are not contagious may be buried on site under the supervision of a veterinarian licensed to practice veterinary medicine in the State of Texas;
- (iv) carcasses of animals intentionally exposed to pathogens which are not contagious may be sent to a rendering plant;
- (v) moist heat disinfection followed by deposition in a sanitary landfill;
- (vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(B) Body parts of animals intentionally exposed to pathogens shall be subjected to one of the following methods of treatment and disposal:

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) steam disinfection followed by grinding and discharging into a sanitary sewer system;
- (iii) incineration followed by deposition of the residue in a sanitary landfill;
- (iv) body parts of animals intentionally exposed to pathogens which are not contagious may be buried on site under the supervision of a veterinarian licensed to practice veterinary medicine in the State of Texas;

- (v) moist heat disinfection followed by deposition in a sanitary landfill;
- (vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(C) Bulk whole blood, serum, plasma, and/or other blood components from animals intentionally exposed to pathogens shall be subjected to one of the following methods of ~~treatment and disposal~~:

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) steam disinfection followed by grinding and discharging into a sanitary sewer system;
- (iii) incineration followed by deposition of the residue in a sanitary landfill;
- (iv) thermal inactivation followed by deposition in a sanitary landfill;
- (v) thermal inactivation followed by grinding and discharging into a sanitary sewer system;
- (vi) chemical disinfection followed by deposition in a sanitary landfill;
- (vii) chemical disinfection followed by grinding and discharging into a sanitary sewer system;
- (viii) bulk blood, serum, plasma, and/or other blood components of animals intentionally exposed to pathogens which are not contagious may be buried on site under the supervision of a veterinarian licensed to practice veterinary medicine in the State of Texas;
- (ix) moist heat disinfection followed by deposition in a sanitary landfill;
- (x) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (xi) an approved alternate treatment process followed by deposition in a sanitary landfill.

(D1) Bedding of animals intentionally exposed to pathogens shall be subjected to one of the following methods of treatment and disposal :

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) incineration followed by deposition of the residue in a sanitary landfill;
- (iii) bedding of animals intentionally exposed to pathogens which are not contagious may be buried on site under the supervision of a veterinarian licensed to practice veterinary medicine in the State of Texas;
- (iv) moist heat disinfection followed by deposition in a sanitary landfill;

(v) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(vi) an approved alternate treatment process followed by deposition in a sanitary landfill.

(2) Bulk human blood, bulk human blood products, and bulk human body fluids. Bulk human blood, blood products, and body fluids shall be subjected to one of the following methods of ~~treatment and disposal~~:

(A) discharging into a sanitary sewer system;

(B) steam disinfection followed by deposition in a sanitary landfill;

(C) incineration followed by deposition of the residue in a sanitary landfill;

(D) chemical disinfection followed by deposition in a sanitary landfill;

(E) chemical disinfection followed by grinding and flushing into a sanitary sewer system;

(F) thermal inactivation, followed by deposition in a sanitary landfill;

(G) thermal inactivation, followed by grinding and discharging into a sanitary sewer system;

(H) moist heat disinfection followed by deposition in a sanitary landfill;

(I) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(J) an approved alternate treatment process followed by deposition in a sanitary landfill.

(3) Microbiological waste. Microbiological waste shall be subjected to one of the following methods of treatment and disposal.

(A) Discarded cultures and stocks of infectious agents and associated biologicals shall be subjected to one of the following methods of treatment and disposal:

(i) steam disinfection followed by deposition in a sanitary landfill;

(ii) incineration followed by deposition of the residue in a sanitary landfill;

(iii) thermal inactivation followed by deposition in a sanitary landfill;

(iv) chemical disinfection followed by deposition in a sanitary landfill;

(v) moist heat disinfection followed by deposition in a sanitary landfill;

(vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(B) Discarded cultures of specimens from medical, pathological, pharmaceutical, research, clinical, commercial, industrial and veterinary laboratories shall be subjected to one of the following methods of treatment and disposal:

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) incineration followed by deposition of the residue in a sanitary landfill;
- (iii) thermal inactivation followed by deposition in a sanitary landfill;
- (iv) chemical disinfection followed by deposition in a sanitary landfill;
- (v) moist heat disinfection followed by deposition in a sanitary landfill;
- (vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(C) Discarded live and attenuated vaccines, but excluding the empty containers thereof, shall be subjected to one of the following methods of treatment and disposal:

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) incineration followed by deposition of the residue in a sanitary landfill;
- (iii) thermal inactivation followed by deposition in a sanitary landfill;
- (iv) chemical disinfection followed by deposition in a sanitary landfill;
- (v) moist heat disinfection followed by deposition in a sanitary landfill;
- (vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(D) Discarded disposable culture dishes shall be subjected to one of the following methods of treatment and disposal.

(i) All discarded, unused disposable culture dishes shall be disposed of in accordance with ~~Title 30, Texas Administrative Code, Chapter 330.~~ [30 TAC Chapters 326 and 330.](#)

(ii) Discarded, used disposable culture dishes shall be subjected to the following methods of treatment and disposal:

- (I) steam disinfection followed by deposition in a sanitary landfill;
- (II) incineration followed by deposition of the residue in a sanitary landfill;

- (III) thermal inactivation followed by deposition in a sanitary landfill;
- (IV) chemical disinfection followed by deposition in a sanitary landfill;
- (V) moist heat disinfection followed by deposition in a sanitary landfill;
- (VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (VII) an approved alternate treatment process followed by deposition in a sanitary landfill.

(E) Discarded disposable devices used to transfer, inoculate or mix cultures shall be subjected to one of the following methods of treatment and disposal:

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) incineration followed by deposition of the residue in a sanitary landfill;
- (iii) thermal inactivation followed by deposition in a sanitary landfill;
- (iv) chemical disinfection followed by deposition in a sanitary landfill;
- (v) moist heat disinfection followed by deposition in a sanitary landfill;
- (vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(4) Pathological waste. Pathological waste shall be subjected to one of the following methods of treatment and disposal.

(A) Human materials removed during surgery, labor and delivery, autopsy, embalming, or biopsy shall be subjected to one of the following methods of treatment and disposal:

- (i) body parts, other than fetal tissue:
  - (I) interment;
  - (II) incineration followed by deposition of the residue in a sanitary landfill;
  - (III) steam disinfection followed by interment;
  - (IV) moist heat disinfection, provided that the grinding/shredding renders the item as unrecognizable, followed by deposition in a sanitary landfill;
  - (V) chlorine disinfection/maceration, provided that the grinding/shredding renders the item as unrecognizable, followed by deposition in a sanitary landfill; or

(VI) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(ii) tissues~~-or fetuses-~~, other than fetal tissue:

- (I) incineration followed by deposition of the residue in a sanitary landfill;
- (II) grinding and discharging to a sanitary sewer system;
- (III) interment;
- (IV) steam disinfection followed by interment;
- (V) moist heat disinfection followed by deposition in a sanitary landfill;
- (VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(iii) organs, other than fetal tissue:

- (I) incineration followed by deposition of the residue in a sanitary landfill;
- (II) grinding and discharging to a sanitary sewer system;
- (III) interment;
- (IV) steam disinfection followed by interment;
- (V) moist heat disinfection followed by deposition in a sanitary landfill;
- (VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(iv) bulk human blood and bulk human body fluids removed during surgery, labor and delivery, autopsy, embalming, or biopsy:

- (I) discharging into a sanitary sewer system;
- (II) steam disinfection followed by deposition in a sanitary landfill;
- (III) incineration followed by deposition of the residue in a sanitary landfill;
- (IV) thermal inactivation followed by deposition in a sanitary landfill;

- (V) thermal inactivation followed by grinding and discharging into a sanitary sewer system;
- (VI) chemical disinfection followed by deposition in a sanitary landfill;
- (VII) chemical disinfection followed by grinding and discharging into a sanitary sewer system;
- (VIII) moist heat disinfection followed by deposition in a sanitary landfill;
- (IX) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (X) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(v) fetal tissue, regardless of the period of gestation, except as provided by §1.133 of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services):

(I) interment;

(II) incineration followed by interment; or

(III) steam disinfection followed by interment.

(B) The products of spontaneous or induced human abortion shall be subjected to one of the following methods of treatment and disposal:

~~—(i) body parts, tissues, or organs~~(i) fetal tissue, regardless of the period of gestation, except as provided by §1.133 of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services):

~~—(I) grinding and discharging to a sanitary sewer system;~~

~~—(H(I)) incineration followed by~~ ~~deposition of the residue in a sanitary landfill;~~interment;

~~—(HH(II)) steam disinfection followed by interment; or~~

~~—(IV(III)) interment;~~

~~—(V) moist heat disinfection followed by deposition in a sanitary landfill;~~

~~—(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or~~

~~—(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;~~

(ii) blood and body fluids:

- (I) discharging into a sanitary sewer system;
- (II) steam disinfection followed by deposition in a sanitary landfill;
- (III) incineration followed by deposition of the residue in a sanitary landfill;
- (IV) thermal inactivation followed by deposition in a sanitary landfill;
- (V) thermal inactivation followed by grinding and discharging into a sanitary sewer system;
- (VI) chemical disinfection followed by deposition in a sanitary landfill;
- (VII) chemical disinfection followed by grinding and discharging into a sanitary sewer system;
- (VIII) moist heat disinfection followed by deposition in a sanitary landfill;
- (IX) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(X) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(iii) any other tissues, including placenta, umbilical cord and gestational sac;

(I) grinding and discharging to a sanitary sewer system;

(II) incineration followed by deposition of the residue in a sanitary landfill;

(III) steam disinfection followed by interment;

(IV) interment;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

~~—(X)~~ (VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill.

(C) Discarded laboratory specimens of blood and/or tissues shall be subjected to one of the following methods of treatment and disposal:

- (i) grinding and discharging into a sanitary sewer system;
- (ii) steam disinfection followed by deposition in a sanitary landfill;



(iii) steam disinfection followed by grinding and discharging into a sanitary sewer system;

(iv) incineration followed by deposition of the residue in a sanitary landfill;

(v) moist heat disinfection followed by deposition in a sanitary landfill;

(vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(vii) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill.

(D) Anatomical remains shall be ~~subjected to one of the following methods of treatment and disposal:~~ disposed of in a manner specified by §479.4 of this title (relating to Final Disposition of the Body and Disposition of Remains).

~~—(i) interment;~~

~~—(ii) incineration followed by interment; or~~

~~—(iii) steam disinfection followed by interment.~~

(5) Sharps.

(A) All discarded unused sharps shall be disposed of in accordance with ~~Title 30, Texas Administrative Code, Chapter 330.~~ 30 TAC Chapters 326 and 330.

(B) Contaminated sharps shall be subjected to one of the following methods of treatment and disposal.

(i) Hypodermic needles, and hypodermic syringes with attached needles, shall be subjected to one of the following methods of treatment and disposal:

(I) chemical disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(II) steam disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant container followed by deposition in a sanitary landfill;

(III) incineration, and if the item can cause puncture wounds, placement in a puncture-resistant container followed by deposition in a sanitary landfill;

(IV) encapsulation in a matrix which will solidify and significantly reduce the possibility of puncture wounds followed by deposition in a sanitary landfill;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable and can no longer cause puncture wounds, followed by deposition in a sanitary landfill.

(ii) Razor blades, disposable razors, and disposable scissors used in surgery, labor and delivery, or other medical procedures; and scalpel blades shall be subjected to one of the following methods of treatment and disposal:

(I) chemical disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(II) steam disinfection, and if the item can cause puncture wounds, placement in a puncture resistant container followed by deposition in a sanitary landfill;

(III) incineration, and if item can cause puncture wounds, placement in a puncture-resistant container followed by deposition in a sanitary landfill;

(IV) encapsulation in a matrix which will solidify and significantly reduce the possibility of puncture wounds followed by deposition in a sanitary landfill;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable and can no longer cause puncture wounds, followed by deposition in a sanitary landfill.

(iii) Intravenous stylets and rigid introducers (e.g., J wires) shall be subjected to one of the following methods of treatment and disposal:

(I) chemical disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(II) steam disinfection, and if the item can cause puncture wounds, placement in a puncture resistant, leak-proof container followed by deposition in a sanitary landfill;

(III) incineration, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(IV) encapsulation in a matrix which will solidify and significantly reduce the possibility of puncture wounds, followed by deposition in a sanitary landfill;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable and can no longer cause puncture wounds, followed by deposition in a sanitary landfill.

(iv) Glass pasteur pipettes, glass pipettes, specimen tubes, blood culture bottles, and microscope slides, and broken glass from laboratories shall be subjected to one of the following methods of treatment and disposal:

(I) chemical disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(II) steam disinfection, and if the item can cause puncture wounds, placement in a puncture resistant container followed by deposition in a sanitary landfill;

(III) incineration, and if the item can cause puncture wounds, placement in a puncture-resistant container followed by deposition in a sanitary landfill;

(IV) encapsulation in a matrix which will solidify and significantly reduce the possibility of puncture wounds followed by deposition in a sanitary landfill;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable and can no longer cause puncture wounds, followed by deposition in a sanitary landfill.

(v) Tattoo needles, acupuncture needles, and electrolysis needles shall be subjected to one of the following methods of treatment and disposal:

(I) chemical disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(II) steam disinfection, and if the item can cause puncture wounds, placement in a puncture resistant, leak-proof container followed by deposition in a sanitary landfill;

(III) incineration, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(IV) encapsulation in a matrix which will solidify and significantly reduce the possibility of puncture wounds, followed by deposition in a sanitary landfill;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable and can no longer cause puncture wounds, followed by deposition in a sanitary landfill.

(b) Records. The facility treating the wastes shall maintain records to document the treatment of the special waste from health care-related facilities processed at the facility as to method and conditions of treatment in accordance with ~~Title 30, Texas Administrative Code, 30 TAC~~ Chapter ~~330.326.~~ 30 TAC Chapter 330.326.

(c) Facility responsibility. The facility treating the wastes shall be responsible for establishing the conditions necessary for operation of each method used at the facility to insure the reduction of microbial activity of any waste treated according to the manufacturer's specifications and according to any approval granted by the department.

**§ 1.137. Enforcement.**

The appropriate regulatory programs of the department shall incorporate the definition and methodology contained in these provisions into their respective general program rules and shall formulate and present for the ~~board~~Executive Commissioner's consideration such additional rules as are necessary for the internal collection, storage, handling, movement, and treatment of special waste from health care-related facilities generated within or by the following facilities or activities:

- (1) abortion clinics;
- (2) ambulatory surgical centers;
- (3) birthing centers;
- (4) emergency medical service providers;
- ~~(5) home and community support services agencies;~~
- (5) end stage renal disease facilities;
- (6) freestanding emergency medical care facilities;
- (7) hospitals;
- ~~(7)~~ special residential care facilities; and
- ~~(8)~~ tattoo studios.